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COMMENTS ON RoC REVIEW PROCESS

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NTP's Proposal



- **Reduces, rather than enhances, transparency**
 - Adopts a discretionary, “tailored” approach to conducting cancer evaluation
 - Denies public an opportunity to review monograph until after interagency review (NTP discretion)
 - Prevents review of interagency comments
 - Eliminates BSC review of monograph & listing recommendation (NTP discretion)
- **Reduces the opportunity for meaningful public participation**
 - Eliminates public comment on background document
 - Drops the requirement to respond to public comments
- **Compromises the scientific integrity and rigor of the RoC process**
 - Replaces background document with “concept paper”
 - Removes BSC from all but substance selection (NTP discretion)
 - Blurs science/policy earlier in the process
 - NTP develops the listing recommendation
 - Further insulates NTP & RoC reviewers from scientific debate

Clarification of Listing Criteria

Revise the listing criteria as applied to “known” carcinogens to include the requirement for –

- a biologically plausible mechanism,
- an assessment of the quality of the study, or studies, on which the determination is based
- a weight-of-evidence evaluation of all the available information

Focus on Scientific Decision-Making

- **Employ a consistent weight-of-evidence framework**
 - formulated upon a hypothesis-based, mode-of-action evaluation
 - data from all relevant studies can be systematically reviewed and given appropriate weight
- **Incorporate a standardized approach to evaluating studies**
 - such as that recommended by the National Academy of Sciences

Review Process

- Conduct an independent peer review
 - Expert panel selected by a transparent process (e.g., NAS panel selection process)
 - Ensure appropriate level & breadth of expertise
- Provide a summary of the main points of controversy
- Allow panel to make the listing recommendation
 - Not NTP
 - Recommendation based on objective and transparent criteria

Public Review & Comment

- Allow for public comment at each stage of the review process, including -
 - selection of substances
 - draft monograph (w/o listing recommendation)
 - revised draft monograph
 - final draft monograph
- Prepare a response to comments at each stage